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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,601	09/15/2003	Marton Klein	1/1393	2344
28501	7590	04/14/2005		EXAMINER CYGAN, MICHAEL T
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			ART UNIT 2855	PAPER NUMBER
DATE MAILED: 04/14/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/662,601 Michael Cygan	KLEIN ET AL. Art Unit 2855

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 February 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-26,30,31 and 33-40 is/are rejected.
- 7) Claim(s) 27-29 and 32 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 21-24, 30, 31, 37, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veillard (FR 2,193,478) in view of Vinton (US 4,803,868). Veillard teaches a method of checking the leaktightness of a sealed container [1] having a flange [4] and holding a gas (possibly at low pressure through application of a vacuum), comprising the steps of placing the sealed container in a tank containing a tracer gas such as helium. After an amount of time, the sealed container is removed from the tank, the container is opened, and a sample of the gas inside the container is taken and analyzed at least qualitatively for the presence of the tracer gas to determine leaks. See entire document, especially in the English language translation at page 2 lines 3-8 and the last four paragraphs which describe the process. Veillard teaches the claimed invention except for the sealed containers holding pharmaceutical substances and comprising foil-covered blister packs.

Vinton teaches a method of leak testing hermetically sealed foil-covered blister packs holding pharmaceutical substances; see column 1 lines 6-16 and column 2 lines 30-41. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use hermetically sealed foil-covered blister packs holding pharmaceutical substances as the sealed containers in the method taught by Veillard to perform leaktightness tests, since Vinton teaches that it is "desirable for pharmaceutical pill packs to be hermetically sealed" and for tests to be "performed during the packaging process to determine that the packaging has properly been carried out"; see column 1 lines 11-15.

The temperature of the applied Veillard (FR 2,193,478) and Vinton (US 4,803,868) references is assumed to be ambient (ca. 20-40 °C), since no heating or other temperature description was given in the references.

Alternatively, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed temperature range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art; see *In re Aller* 105 USPQ 233.

2. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veillard (FR 2,193,478) in view of Vinton (US 4,803,868) as applied to claim 3 above, and further in view of Krahn (US 2001/0016059 A1). The

claimed invention is considered to be taught except for the use of a polypropylene container having an aluminum foil cover. Krahn teaches the leak testing or blister packages, which are stated to consist of a polypropylene container having an aluminum foil cover; see column 1, paragraphs 1 and 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polypropylene container having an aluminum foil cover as taught by Krahn in the invention taught by Veillard in view of Vinton, since (while Viton is silent to the nature of the blister packs) Krahn teaches that such a composition is standard in the art for blister packs.

3. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veillard (FR 2,193,478) in view of Vinton (US 4,803,868) as applied to claim 21 above, and further in view of Achter (US 5,939,619). The claimed invention is considered to be taught except for the use of the claimed pressure ranges. Achter teaches the application of appropriate pressure ranges when introducing a tracer gas into a sealed flexible package containing a metal foil; see column 5 lines 10-13 and column 3 lines 20-39. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed pressure ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art; see *In re Aller* 105 USPQ 233.

4. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Veillard (FR 2,193,478) in view of Vinton (US 4,803,868) as applied to claim 1 above, and further in view of Westbrook (US 6,067,844). The claimed invention is considered to be taught except for the opening and removal of the gas being carried out in a single step. Westbrook teaches a leaktightness test in which a tracer gas is analyzed from within a sealed chamber wherein the opening and removal of the gas being carried out in a single step; see column 7 lines 1-30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a single step method as taught by Westbrook in the invention taught by Veillard to sample the gas, since this would eliminate the presence of interferences (introduced with ambient air during the opening of the container) in the sampled air being analyzed, thus reducing sources of error.

#### ***Allowable Subject Matter***

5. Claims 27-29 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, since the prior art neither discloses nor fairly teaches the structural and/or temperature

limitations set forth in these claims in combination with the other recited limitations.

***Response to Arguments***

6. Applicant argues that Veillard's container is not sealed as claimed, since it uses a plug. However, the claim encompasses even temporarily sealed containers, and is therefore met by the combination applied in the rejection.
7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the Vinton reference is applied only for the teaching of the desirability of testing sealed foil-covered blister packs holding pharmaceutical substances.
8. Furthermore, Vinton notes that such testing is desirable in an on-going packaging process; see column 1 lines 6-15.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Cygan whose telephone number is (571) 272-2175. The examiner can normally be reached on 8:30-6 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Lefkowitz can be reached on 571-272-2180. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL CYGAN, PH.D.  
PRIMARY EXAMINER